K121613

510(k) Summary for the Fresenius Kabi Agilia Infusion System

MAY 0-1 2013

1. SUBMITTER/510(K) HOLDER

Fresenius Kabi AG
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Date Prepared: May 31, 2012

2. DEVICE NAME

Proprietary Name:	Agilia Infusion System
Common/Usual Name:	Infusion pump system
Classification Name:	Infusion pumps
	Intravascular administration sets

3. PREDICATE DEVICES

- K062700/K083689 B. Braun Medical, Inc., Infusomat® Space Volumetric Infusion Pump System

4. DEVICE DESCRIPTION

The Agilia Infusion System is composed of the following components:

- Volumat MC Agilia infusion pump
- Volumat Lines administration sets
  - 16 sterile administration sets, including 2 for transfusions and 1 auxiliary line
- Link+ Agilia racks, three options:
  - Link4+
  - Link6+
  - Link8+
- Vigilant Drug'Lib Agilia: dose error reduction software (DERS)
  - Accessories:
    - Agilia Duo
    - Agilia USB cable

- Link+ Agilia Nurse Call cable
- Agilia RS232 cable
- Link+ Agilia Ethernet cross-over cable
- Link+ Agilia USB Cable

The Volumat MC Agilia infusion pump is a peristaltic infusion pump which can be installed on a rail or pole, or on a flat surface. The system is configurable by the user, ranging from a configuration with a single Volumat MC Agilia infusion pump to multiple-pump configurations utilizing Link+ racks connected to a Hospital Information System (HIS). A series of two pumps may be configured using the Agilia DUO accessory, or a series of 4, 6, or 8 pumps may be mounted on the Link+ Agilia rack to centralize power supply and data communication. Vigilant Drug'Lib Agilia dose error reduction software (DERS) (optional) is installed on a PC platform for communication with the pump via a USB cable.

5. INDICATION FOR USE/INTENDED USE

The Agilia Infusion System is a transportable equipment intended to be used in healthcare facilities environment by healthcare trained professionals according to hospital protocols on adults, pediatrics and neonates human patients to administer via a single channel or mounted on a multiple channels rack accessory:

- Intermittent or continuous delivery of parenteral fluids (solutions, colloids, parenteral nutrition) and medications (including but not limited to diluted drugs, chemotherapy) through clinically accepted IV routes of administration.
- Transfusion of blood and blood derivatives products.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

Both the proposed Agilia Infusion System and the predicate Infusomat® Space Volumetric Infusion System have a similar overall design, consisting of an external and transportable infusion pump with accessories including dedicated administration sets, DERS, and a rack for mounting several individual pumps to provide centralized power and alarms replication.

The proposed Volumat MC Agilia and Infusomat® Space infusion pumps are both microprocessor-controlled, linear peristaltic pumps that achieve infusion in an identical manner and have similar operational features, alarms, and indicators. The technological and performance characteristics of the proposed and the predicate device are also similar. The two systems have equivalent accuracies and infusion

volume capacities, as well as similar rate ranges. Both pumps detect upstream and downstream occlusion by means of specific sensors. In addition, both pumps offer the possibility to limit the same drug parameters in DERS mode and assure safety in an equivalent way.

The Link+ Agilia and SpaceStation from B. Braun are both rack systems that are intended to power mounted IV pumps and ensure infusion data communication to external HIS. Link+ Agilia and B. Braun SpaceStation support hospital wired network connection using Ethernet standard and to export patient infusion data to third party systems. Link+ Agilia does not support RF wireless network connection in order to limit radio frequency emissions at the bedside.

Both the Vigilant Drug'Lib Agilia DERS and B. Braun Drug List Editor software applications are intended to secure the administration of drugs with configurable drug limits according to clinical practice. Vigilant Drug'Lib Agilia can upload up to 19 different drug libraries to pumps. The drug library of the Agilia Infusion System can be adapted to a specific care area (association of a drug library and a set of device configurations). Vigilant Drug'Lib Agilia manages up to 19 Care Areas. The predicate device manages up to 15 drug categories that serve to classify the drugs - from a drug pool or to create a subset of drugs with different concentrations.

The administration sets provided for use with the proposed and predicate infusion systems have equivalent technological characteristics, with various component combinations and materials for specific medical applications. Both the proposed and predicate administration sets include tubing sets, connectors, filters, etc. that comply with industry requirements and standards. Technological characteristics such as tubing diameter and length, filter sizes, Luer Lock connectors, etc., are comparable for the proposed and predicate devices and conform to industry standards.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Nonclinical testing performed to support the performance and safety claims for the Agilia Infusion System includes, but is not limited to, the following:

- Biocompatibility testing according to ISO 10993-1, ISO 8536, ISO 594 for Volumat Lines
- Hardware and software verification and validation testing including testing to relevant industry standards (e.g. IEC 60601-2-24, ISO 60601-1-8, IEC 62304, ISO 8536, ISO 594)

- Testing to industry standards for electrical safety and electromagnetic compatibility (e.g., IEC 60601-1, IEC 60601-1-2)
- Sterilization validation, shelf life testing, packaging and transport validation

Usability assessments were conducted in a simulated use environment in accordance with IEC 62366 to optimize the safety of the device design and validate the usability of the system.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical testing was performed in support of this premarket notification.

9. SUMMARY OF OTHER INFORMATION

Per the Guidance for Industry and FDA Staff, Total Product Life Cycle: Infusion Pump – Premarket Notification [510(k)] Submissions (April 23, 2010) (TPLC Infusion Pump Guidance), a safety assurance case is provided for the Agilia Infusion System.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Non-clinical testing, as well as a detailed clinical evaluation involving an extensive series of usability tests, supports the performance and safety claims for the Agilia Infusion System. The similarities in intended use, operational characteristics, technological characteristics, and performance characteristics between the proposed Agilia Infusion System and the predicate Infusomat Space Volumetric Infusion Pump System lead to a conclusion of substantial equivalence between the proposed and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2013

Fresenius Kabi AG
C/O Ms. Cheryl Roscher
Three Corporate Drive
LAKE ZURICH Illinois 60047

Re: K121613
Trade/Device Name: Agilia Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: April 26, 2013
Received: April 29, 2013

Dear Ms. Roscher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

K121613

Device Name:

Agilia Infusion System

Indication(s) for Use:

The Agilia Infusion System is a transportable equipment intended to be used in healthcare facilities environment by healthcare trained professionals according to hospital protocols on adults, pediatrics and neonates human patients to administer via a single channel or mounted on a multiple channels rack accessory:

• Intermittent or continuous delivery of parenteral fluids (solutions, colloids, parenteral nutrition) and medications (including but not limited to diluted drugs, chemotherapy) through clinically accepted IV routes of administration.

• Transfusion of blood and blood derivatives products. Note that for transfusion procedures, use of a special administration set is required.

Prescription Use: X	AND/OR	Over-the-counter Use:
(21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sajjad H. Syed

Digitally signed by Sajjad H. Syed
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sajjad H. Syed, 0.9.2342.19200300.100.1.1=2000601742
Date: 2013.04.30 14:17:40 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121613